

## **REMARKS**

Amendments to the claims have been made to respond to the issues and concerns raised in the Office Action and to clarify aspects in the claims. Claim 155 has been newly added. In light of the previously and currently cancelled claims, it is believed that no additional claim fees are needed.

### 35 U.S.C. § 112 Concerns

Claims 148, 149, 152, and 153 have been newly cancelled. As such, the concerns under 112 are believed to be moot.

### 35 U.S.C. § 103 Concerns

The Office has expressed 35 U.S.C. § 103 concerns to the claims. With respect to independent claim 1, Assignee respectfully disagrees that this claim is obvious over the cited art. Claim 1 includes, *inter alia*, “staining said sperm cells with Hoechst 33342 stain for a period of 30 minutes and separating said sperm cells based upon said sex characteristic into X chromosome bearing and Y chromosome bearing populations.” As background, “the only established and measurable difference between X and Y sperm that is known and has been proved to be scientifically valid is their difference in deoxyribonucleic acid (DNA) content. The X chromosome is larger and contains slightly more DNA than does the Y chromosome. The difference in total DNA between X-bearing sperm and Y-bearing sperm is 3.4% in boar, 3.8% in bull and 4.2% in ram sperm. The amount of DNA in a sperm cell, as in most normal body cells, is stable. Therefore, the DNA content of individual sperm can be monitored and used to differentiate X- and Y-bearing sperm.” (See US Pat. No. 5,135,759, as cited on 01/24/2005). For separating X- and Y-bearing sperm into individual populations, “[a] nontoxic DNA stain must be selected. A preferred stain is Hoechst bis-Benzimide H33342 fluorochrome ... To our knowledge, this fluorochrome is the only DNA binding dye that is nontoxic to sperm. ... The sperm must be incubated with stain at sufficient temperature *and time for staining*

to take place, but under mild enough conditions to preserve viability. Incubation for 1 hr at 35°C was found to be acceptable..." (See US Pat. No. 5,135,759, as cited on 01/24/2005, emphasis added). Thus, for small differences in DNA to be detected between X and Y, the sperm must be adequately stained.

The action cites the combination of WO 02/41906, WO 01/37655 in view of each Tardif and Ellington supported by Padilla and in further view of each WO 02/28311 and Lindsey as making the claimed invention obvious. As noted in the action the '906 and '655 references do not teach staining for a period of 30 minutes. Specifically, the '906 reference discusses staining, "form a lower limit of about 1 hour since effective staining under appropriate conditions of temperature and pH can be achieved with that incubation period to about 18, 24, or more hours ..." (See WO02/41906 page 16, lines 4-6). As such this reference makes it clear that staining for less than one hour would not be effective for later separation of sperm cells into X chromosome bearing and Y chromosome bearing populations. Also, the '655 reference discusses staining with Hoechst 33342 for 60 minutes. Again, there is no indication that staining of sperm for later separation of populations would work at a less time in this reference.

The action states that the Tardif reference teaches staining sperm cells with Hoechst 33342 for a period of 30 minutes. While the Tardif reference does stain sperm cells with Hoechst 33342, it is respectfully submitted that the Tardif reference is not using stain, specifically Hoechst 33342 to separate sperm cells into X chromosome bearing and Y chromosome bearing populations. The stained sperm cells of the Tardif reference were analyzed with CASA (computer-assisted sperm analysis) to evaluate the stained semen and not to sort them. As stated in the Tardif reference, "[i]n conclusion, bull sperm can be stained with Hoechst 33342 dye at concentrations that permit the Hamilton Thorne unit, equipped with appropriate UV optics, to discriminate accurately between sperm and nonspERM particles. ... Thus, the capability of distinguishing between sperm and nonspERM interfering particulate material expands the opportunity to study sperm function under a variety of conditions and to relate these conditions to the fertilizing potential of the sperm." As such, it is noted that this reference does not take

into account staining of sperm cells for separation into X and Y chromosome bearing populations. One skilled in the art would understand from reading this article that the stain experiments and tests would not be applicable to separating parameters for sperm cells as this reference does not mention separation at all.

With respect to the present invention, it was unexpected to determine that by decreasing the incubation period to stain sperm cells from the conventional period of 60 minutes to a 30 minute period can decrease percentage of dead sperm cells, and increase resolution of X-chromosome bearing sperm cells from Y-chromosome bearing sperm cells. It is the nexus between the stain time and resolution between X and Y chromosome bearing sperm cells which allows the present application to work. It was not known prior to this invention that a shorter stain time would still provide adequate staining of the sperm cells in order to effectively separate the X and Y chromosome bearing sperm cells. (See the specification and figures, specifically Figure 4 for evidence). In conclusion, it is submitted that the present invention of claim 1 yields unexpectedly improved properties not present in the prior art and that the references being relied upon would not enable a skilled artisan to produce the claimed invention.

It is respectfully submitted that independent claim 1 and all the claims made ultimately dependent thereon are novel and non-obvious. See 37 C.F.R. §1.75(c). Should the office require further explanation, the Assignee stands ready to supplement the above remarks if necessary.

Additional Information

The amendments submitted herein should be understood to be made as a practicality only, and should not to be construed as creating any situation of file wrapper estoppel or the like as all rights are expressly reserved and may be pursued in this or other applications, such as divisionals, continuations, or continuations-in-part if desired. Relatedly, it should be understood that the amendments made herein are made for tangential issues of clarity and as a matter of the Office's convenience or expedience

only. The amendments should not be interpreted as an action that in any way surrenders a particular equivalency, surrenders any right to patent coverage, or otherwise limits any rights which the Assignee may now or hereafter assert. It should be understood that, unless and to the extent deemed broadened by this amendment, and even as amended, the Assignee expressly reserves all rights, including but not limited to: all rights to maintain the scope of literal coverage with respect to any element as may have existed under the language previously presented, all rights to maintain the scope of equivalency coverage as may have existed under the language previously presented, and all rights to re-present the prior language at any time in this or any subsequent application. To the extent currently foreseeable, no change or reduction in direct or equivalency coverage is believed to exist, and no change or reduction in direct or equivalency coverage is intended through the presentation of this amendment.

Further, the office and any third persons interested in potential scope of this or subsequent applications should understand that broader claims may be presented at a later date in this or a continuation in spite of any preliminary amendments, other amendments, claim language, or arguments presented, thus there is not intention to disclaim or surrender any potential subject matter. It should be understood that such broader claims may require that any relevant prior art that may have been considered may need to be revisited since it is possible that to the extent any amendments, claim language, or arguments presented in this application are considered as made to avoid such prior art, such reasons may be eliminated by later presented claims or the like. Both the examiner and any person otherwise interested in existing or later coverage or considering the possibility of an indication of disclaimer or surrender of potential coverage, should be aware that no such surrender or disclaimer is intended or exists in this application. Limitations such as arose in *Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313 (Fed. Cir 2007), or the like are expressly not intended in this or any subsequent matter related.

### Conclusion

The Assignee, having addressed each of the concerns raised in the Office Action,

respectfully requests reconsideration and withdrawal of the rejections and objections to the application. Allowance of the claims is requested at the Office's earliest convenience.

Dated this 1<sup>st</sup> day of September, 2009.

Respectfully Submitted,  
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